IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

THE PSC'S SUR-REPLY TO REPLY IN SUPPORT OF MOTION FOR ORDER REQUIRING PRESERVATION OF EXPLANTED MESH

Defendants' position is untenable legally and factually. Legally, plaintiffs are under no greater duty to preserve explant tissue than are defendants. Plaintiffs do not possess or control medical specimens held by third party health care providers. Defendants' motion is, in essence, an attempt to create a duty where none otherwise exists, thereby giving defendants grounds, they hope, to secure dismissal if something happens to explanted tissue. This Court should decline defendants' invitation to create new law. And if defendants are right that plaintiffs have a duty to preserve such materials, there is no need for the vague order that defendants propose, which would do nothing more than re-affirm that duty.

Factually, preservation of thousands of specimens would generate onerous burdens on health care providers who ought to be able to produce the tissue to either side and be done with the matter. That is, if either side wishes a guarantee that it may test the material, it should order the material now and either test it or preserve it for testing, maintaining a sufficient sample for the adversary to do the same. But that should be a task for an interested party, not hospitals and physicians who have no stake in these proceedings. The imposition of an overarching

preservation burden on health care providers undermines their ability to provide high quality care and imposes a burden on them that no third party should bear, much less a third party that provides such a vital public health service.

Plaintiffs have agreed to be bound by the order in the *Bard* litigation that (a) specifies the conditions under which tissue will be preserved so that health care providers will not be in contempt and plaintiffs will not have their claims dismissed if substantial compliance occurs but tissue nonetheless is lost, (b) shifts the burdensome tasks involved to a third party vendor specializing in tissue preservation to and (c) limits preservation requirements to cases selected for bellwether status.[1] Plaintiffs maintain their commitment to follow this order. But the broad-based order that defendants propose – "Preserve everything by doing everything you need to" – is ambiguous, overreaching and unfair to physicians and plaintiffs alike. Plaintiffs would never have consented to an order in *Bard* or any other litigation that involves such a vague, sweeping mandate, particularly when the scope of the order exceeds what is authorized by the Rules.

1. <u>Defendants seek to create an onerous burden on plaintiffs that the law does not recognize.</u>

Plaintiffs have no greater duty to ensure that medical facilities preserve explanted tissue than defendants do. Defendants' only argument otherwise is the unsupported statement:

> Plaintiffs cannot seriously contest that they have a duty to preserve the explanted mesh material. They are plaintiffs in this ongoing litigation, and this critical piece of evidence is in their custody or control.

[1] Plaintiffs' Opposition ("Oppos."), Ex. A. The only modification plaintiffs have suggested involves the use of a saline solution which is not the industry standard for preserving human explants. Neutral-buffered formalin (NBF) is what virtually 100% of the mesh samples to date have been preserved in by pathology departments around the country. In fact, the Bard defendants and PSC counsel have worked to revise this section of the *Bard* PTO given the destructive nature of storing human tissue in normal saline.

(Motion at 2). Defendants are flatly wrong, which is undoubtedly why their argument contains no citation to any type of law -- only hyperbole.

While federal case law is unavailable on explanted tissue specifically, it is abundant with regard to medical records generally. Contrary to defendants' claim, plaintiffs do not control their medical files, even though those files can be obtained by subpoena with a proper authorization form. In actuality, either party can obtain those files, including pathological materials, with a proper subpoena. The health care provider controls the records, though, notwithstanding the fact that they relate to the plaintiff's care. Thus, plaintiffs have no greater duty to test or facilitate the testing of pathological material than do defendants.

In *Clark v. Vega Wholesale Inc.*, 181 F.R.D. 470 (D. Nev. 1998), the court noted that the essence of "control," for discovery purposes, refers to a party's legal right of access to materials. The court held that a plaintiff has no legal right to medical records held by a third party entity, despite the fact that the plaintiff could obtain them with a valid authorization. Indeed, "medical care providers maintain custody or control of medical records." *Id.* at 472 (citation omitted). In a subsequent decision, the same court referred to a line of cases holding that "a patient does not have control of medical records that are in the possession, custody or control of his medical providers." *Powell v. Texvana, Inc.*, No. 2:09-cv-01079-LDG-GWF, 2010 WL 4791507, at *1 (D. Nev. Nov. 18, 2010). Moreover, "the party seeking the records can obtain them by serving a subpoena on the medical provider." *Id.*

Numerous other courts concur. *See, e.g., Neal v. Boulder*, 142 F.R.D. 325, 327 (D. Colo. 1992) ("Plaintiffs do not have custody of the medical records being sought."); *Zavala-Basquez v. Allstate Indem. Co.*, No. C8-5673BHS, 2009 WL 3063078, at *2 (W.D. Wash. Sept. 21, 2009) ("Plaintiffs' DSHS records are not within their control and Defendant has other means of

obtaining the information."); *Greene v. Sears, Roebuck & Co.*, 40 F.R.D. 14, 16 (N.D. Ohio 1966) ("It must be borne in mind that Rule 34 extends only to documents which an adverse party has 'in his possession custody or control.' From the record, it does not appear, and it seems quite unlikely, that any of the [treating physician notes] are now in the possession or custody of the plaintiff or her counsel."); *Dobbey v. Randle*, No. 10 C 3965, 2014 WL 1364428, at *2 (N.D. Ill. Apr. 7, 2014) ("Plaintiff's [unproduced] medical records are in [the Illinois Department of Corrections'] possession, custody, and control."); *U.S. v. Sarras*, 575 F.3d 1191, 1215 (11th Cir. 2009) (a plaintiff's medical records are in the control of the facility holding them).

The fact that plaintiffs have the ability to obtain their medical records via authorization does not change this fundamental fact. After all, plaintiffs' consent does not obligate the provider to produce the records on demand; it simply authorizes the provider to produce them under HIPAA. The provider may still, and certainly in the case of physical specimens typically does, require a subpoena (i.e., a court order) from either party prior to production.

Federal courts have thus held that the ability of a plaintiff to obtain his records with an authorization form does not constitute control for purposes of discovery. As Judge James Seibert of this Circuit wrote:

> This Court agrees with those courts finding that Rule 34 requires an item in a request for production be in the possession, custody, or control of the served party and that medical records held by a physician do not meet this description. The plain language of the Rule provides that a request for production must involve items "which are in the possession, custody or control of the party upon whom the request is served." Fed. R. Civ. P. 34(a). There is no provision in Rule 34 for requesting documents from a party that are possessed by another person. While a patient may be able to request medical records from a physician, the records are not sufficiently within the patient's control to qualify under Rule 34.

Ayers v. Continental Casualty Co., Civ. Act. No. 5:05-CV-95, 2007 WL 1960613, at *7 (N.D.W. Va. July 2, 2007); *see also Pham v. Wal-Mart Stores, Inc.*, No. 2:11-cv-01148-KJD-GWF, 2012

WL 3730565, at *2 (D. Nev. Aug. 28, 2012) ("The Court finds that Plaintiff does not have possession, custody or control of the medical records, and therefore Plaintiff is not obligated to produce such records under Rule 34. Defendants can secure copies of the relevant documents from the appropriate medical provider or state or local agency as readily as Plaintiff."); *Candelaria v. Erickson*, No. 01 Civ. 8594 LTS RLE, 2006 WL 1636817, at *2 (S.D.N.Y. June 8, 2006) ("Since the records at issue are not under [the plaintiff's] possession, custody or control, by executing the updated releases, he would be authorizing only the disclosure of his medical records."); *Clark*, 181 F.R.D. at 672 ("The relationship between the Plaintiff and her doctor is not sufficient to establish control. In fact, the Defendants can secure copies of the requested documents from the custodian of the records as readily as the Plaintiff.").

The whole concept of providing a medical authorization form to defendants in lieu of records belies any notion that plaintiffs control their own records. If plaintiffs did maintain such control, plaintiffs would be obliged to order the records rather than merely provide defendants with the means of doing so.

Seemingly aware of the plethora of case law rejecting their position, defendants hedge their bets by citing two cases dealing with destruction of evidence over which a plaintiff did not maintain control. Initially, defendants cite *Silvestri v. GM*, 271 F.3d 583 (4th Cir. 2001) for the proposition that a plaintiff has an obligation to preserve an automobile involved in an accident even when he does not own the vehicle. (Motion at 2) That it is not at all what *Silvestri* held. In fact, *Silvestri* stands for the proposition that a plaintiff can satisfy his duty to protect evidence he does not possess by notifying the defendant of the existence of his claim and the existence of the evidence, thereby providing the defendant the opportunity to preserve or obtain the evidence

itself. *Id.* at 591 (citation omitted). *Silvestri* thus supports plaintiffs' position rather than defendants' claim. Dispositive to *Silvestri* were the following facts:

> (1) the plaintiff failed even to notify the defendant of his potential claim for three years after the accident;
>
> (2) the plaintiff obtained access to the vehicle and had his expert test it shortly after the accident;
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> (3) the plaintiff's own expert recommended that plaintiff notify defendant of the claim because defendant would need to test the car, but plaintiff declined to do so;
>
> (4) the vehicle provided the only evidence at all of product defect.[2]

Id. at 591-92.[3] None of these facts is present here. Defendants are on notice of the claims at issue and have every opportunity to obtain and test any explanted tissue from any plaintiff now. And there is ample evidence available to both sides regarding plaintiffs' claims.

2. <u>Defendants' motion would be superfluous if a plaintiff's duty to preserve explant tissue already existed.</u>

The disingenuous nature of defendants' motion becomes apparent in their reply brief. In responding to plaintiff's request for an order involving specific procedures by which the parties may preserve explant evidence, defendants respond that no particular mandates should appear in any court order. Plaintiffs already have a duty to preserve the evidence, defendants say. Thus, it is up to plaintiffs, and plaintiffs alone, to determine how to do that.

> It is not Defendants' or the Court's duty to define the time, method, or manner for preservation of Plaintiffs' evidence….It is not the role of the Defendants or the Court to advise Plaintiffs as to how to preserve their evidence. Plaintiffs must take

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[2] The absence of any alternate evidence on which the defendant could rely was crucial to the holding in *Silvestri*. *See Sampson v. City of Cambridge, Md.*, 251 F.R.D. 172, 180 & n. 12 (D. Md. 2008) (discussing *Silvestri*).

[3] *See also Benitez v. Ford Motor Co.*, No. CL-2004-222545, 2005 WL 3476694, at *3 (Va. Cir. Ct. Nov. 23, 2005) (noting the importance of each conclusion to the holding in *Silvestri*).

> whatever steps may be appropriate to preserve this evidence for whatever testing may be required by both Plaintiffs and Defendants.

(Reply at 4)

This makes it apparent that defendants' motion is essentially an exercise in "gotcha." If defendants truly believe it is beyond dispute that plaintiffs have an obligation to preserve explant evidence AND defendants oppose any order regarding how the evidence should be preserved, defendants' motion would be entirely superfluous. It would seek an order for plaintiffs to do what they are already required by law to do. It would thus be analogous to motions *in limine* that seek to exclude inadmissible hearsay or non-authentic documents. Or a motion to compel plaintiff to be truthful in her upcoming deposition. Court orders are not for the purpose of restating the law or rules; they are designed to apply the law to a particular factual setting. By arguing that (a) plaintiffs already have a duty to preserve explant tissue (original motion) and (b) plaintiffs alone should determine how to fulfill that duty (reply), defendants are suggesting that their motion does nothing more than ask the Court to confirm the law as defendants claim it already is – not to apply the law to the facts of this litigation.[4]

Defendants are not naïve litigators. They have not filed the instant motion for the purpose of improperly asking the Court to reaffirm some existing principle of law. They have not simply asked the Court to restate a plaintiff obligation. Defendants are well

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[4] The only part of the motion that would have any relevance at all is the part asking that plaintiffs' experts test only half of the specimen. First of all, that has been the procedure under which the parties have operated to date in both the *Lewis* and *Batiste* matters. Second, if the PSC's proposed order is entered, the mesh specimens will be collected and stored by a third-party laboratory which will follow the instructions on dividing the material in half such that each party will have the same amount of specimen to test. That issue, however, is independent of whether plaintiffs should be compelled to take responsibility for preserving the tissue in the first instance.

aware of the case law above establishing that plaintiffs do not control evidence in the possession of third party health care providers. So, they seek an order that would create a duty that does not otherwise exist. Then, if the evidence were discarded, lost or degraded, defendants could seek an order of dismissal, citing this Court's order as the basis. This is bootstrapping at its worst. Of course, if there were truly a duty by plaintiffs to preserve the material, defendants would be able to file the same motion to dismiss. But there is no such duty, as defendants are apparently aware, hence defendants seek to create the duty with the order that they admit contains no specifics whatever.

3. A universal order requiring preservation in every case would generate undue burden on health care providers, threatening plaintiff and general patient health.

Let's be clear: no one is suggesting that defendants should not be permitted to test explant tissue. In fact, defendants have the ability to subpoena any and all plaintiff pathology and either test it now or preserve it for future testing. But defendants decline to do that. They will undoubtedly claim that is too burdensome. So instead, they seek to shift the burden to health care providers.[5]

The burden is unwarranted. Kate Grayson is the president of Steelgate, Inc., a company specializing in biomedical specimen retrieval and storage that has been intimately involved in preservation efforts in the TVM litigation.[6] Ms. Grayson has testified that hospitals and pathology departments are already overburdened with patient care responsibilities. They have been overwhelmed by the kinds of preservation efforts identified in defendants' motion. They

[5] The PSC draws the Court's attention to Exhibit B of its Response brief which is the proposed Preservation PTO. As that proposed protocol and the attachments thereto delineate, the burden of preserving, storing, photographing, dividing, etc., the bellwether mesh explant samples would be placed on a third-party biorepository that is in the business of handling such complicated and time-consuming tasks.

[6] The discussion in Section 3 herein is supported by Ms. Grayson's declaration, attached as Exhibit B, unless otherwise noted.

could not handle the widespread use of the joint request for preservation that was made in one lawsuit and that defendants cite as an example of the result they seek. (Reply at Ex. A) Moreover, the division of specimens between the parties would be unrealistic, infeasible and cost-prohibitive. Ms. Grayson has outlined the tremendous burdens that would be imposed on a pathology department if it were required to convert each explant specimen into two specimens (or three, if there is tissue remaining for the hospital to retain), handling each specimen differently, depending upon the whims of each party. The manpower involved would overwhelm the departments. The end result would be reversion back to existing practices by the facilities involved. While this might permit defendants to file spoliation motions against plaintiffs, it is not conducive to substantial justice.

Ms. Grayson has also testified as to the burden, cost and frustration of the vague order that defendants support. By contrast, she has indicated that if the parties utilize a third party facility to perform their storage and preservation needs, as the *Bard* order specifies,[7] the burden on hospitals is reduced. This protects patient care while maximizing the viable preservation of tissue. After examining defendants' requested relief and the *Bard* order, Ms. Grayson has testified that the *Bard* order is superior.

Of course, requiring preservation of all tissue of every plaintiff would still be unduly burdensome. If defendants seek immediate preservation of specimens beyond those involved in bellwether cases, it is defendants' responsibility to oversee such preservation and the PSC's proposed preservation protocol sets forth that in that event, defendants would be obligated to follow the same protocol as plaintiffs – request that an agreed-upon, third-party biorespository

[7] Plaintiffs' Oppos., Ex. A at 4.

retrieve, store, photograph and divide the specimens such that both parties have half of the specimen to do with whatever they so choose.

Patient care and litigation fairness should not suffer -- and third party health care institutions, performing a vital good for no stake at all in this litigation, should not be unduly burdened -- because defendants would rather not face the inconvenience of subpoenaing tissue. Defendants have a choice, and they should not be allowed to defer that decision in a manner that disrespects the vital role that hospitals and pathologists perform. Nor should they be permitted to pass their burden onto plaintiffs. The party seeking preservation and testing has the obligation to preserve and test.

For these reasons, plaintiffs ask either that the Court enter no preservation order at all or, in the alternative, the Court enter the same order it entered in the *Bard* litigation less than three months ago.

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Respectfully submitted,

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